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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/506,805

01/19/2005

Andrew Lennard Lewis

Q83534

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23373 7590 02/05/2009
SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER

PURDY, KYLE A

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

02/05/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/506,805	Applicant(s) LEWIS ET AL.	
	Examiner Kyle Purdy	Art Unit 1611	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 21 January 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: _____.
- Claim(s) objected to: _____.
- Claim(s) rejected: 1,7-16,20-28,38 and 42-44.
- Claim(s) withdrawn from consideration: 29-35 and 45-56.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Kyle Purdy/
 Examiner, Art Unit 1611
 February 02, 2009

/David J Blanchard/
 Primary Examiner, Art Unit 1643

Continuation of 11. does NOT place the application in condition for allowance because: 1. Applicants arguments filed 01/21/2009 regarding the rejection of claims 5 and 6 made by the Examiner under 35 USC 103(a) over Lobb et al. (J. Am. Chem. Soc., 2001) in view of Kataoka et al. (Adv. Drug Delivery Rev., 2001), evidenced by Dalmark et al. (J. Gen. Physiol., 1981) have been fully considered and they are found persuasive. This rejection has been overcome by cancellation of the claims.

2. Applicants arguments filed 01/21/2009 regarding the rejection of claims 1, 7-16, 21-28, 38, 43 and 44 made by the Examiner under 35 USC 103(a) over Lobb in view of Kataoka, evidenced by Dalmark have been fully considered but they are not found persuasive.

3. Applicants arguments filed 01/21/2009 regarding the rejection of claims 20 and 42 made by the Examiner under 35 USC 103(a) over Lobb in view of Kataoka and Coessens et al. (Prog. Poly. Sci., 2001), evidenced by Dalmark have been fully considered but they are not found persuasive.

4. The rejection of claims 1, 7-16, 20-28, 38 and 42-44 made by the examiner under 35 USC 103(a) is MAINTAINED for the reasons of record in the office action mailed on 10/20/2008.

5. In regards to the 103(a) rejections above, Applicant asserts the following:

A) Dalmark does not disclose that doxorubicin has a partition coefficient between octanol and water of at least 1.5 because the coefficient is actually between octanol and tris-buffer solution;

B) Lobb has been misinterpreted because Lobb fails to mention any specific drugs; and

C) it would not be obvious to combine Lobb and Kataoka.

6. In response to assertion A, this argument is not persuasive. The Examiner acknowledges that Dalmark teaches that doxorubicin has a coefficient of at least 1.5 between octanol and tris-buffer solution. However, this fact does not mitigate the rejection. The tris-buffer solution is not water per se, but it is an aqueous composition with tris-buffer to maintain a static pH. It is the position of the Examiner that even without the tris-buffer, the coefficient would not substantially change and would remain above 1.5 as the composition would be entirely aqueous. Moreover, doxorubicin would inherently have a partition coefficient of at least 1.5. A partition coefficient is a chemical property of doxorubicin. It is well-known patent law that a chemical compound and its properties are inseparable. See MPEP 2141.02 V. Dalmark was cited to illustrate that the instantly claimed coefficient was known in the art, even though patent law would argue that the compound would necessarily have such a property.

7. In response to assertion B, the Examiner agrees that Lobb fails to teach the micelles as carrying any specific drug. Moreover, it is acknowledged that fibrinogen is not a drug. Applicant is directed to the Examiner's deficiency statement which notes that Lobb fails to specifically teach the nanoparticles as having a hydrophobic drug associated with the core. As Applicant correctly pointed out, Lobb does suggest that their micelles have substantial promise in drug delivery.

8. In response to assertion C, the Examiner respectfully disagrees. It's duly noted that Kataoka teaches copolymers with PEG blocks. Applicant states that a PEG block is distinct from the MPC block as instantly claimed which contain a zwitterionic group and therefore one would not be motivated to combine Lobb and Kataoka. While it's true that PEG is distinct from MPC, this fact does not overcome the applied rejection. Kataoka is relied upon to show that micelles with a hydrophobic core surrounded by a hydrophilic shell are well known in the art and are recognized as useful carriers for hydrophobic drugs. It's taught that doxorubicin is a drug that can be carried by such means. As noted in the previous office action, the hydrophobic core provides a thermodynamically stable environment for doxorubicin wherein the core stabilizes the compound by pi-pi interactions. Thus, one would have been motivated to combine the teachings to arrive at the instantly claimed invention.